

Non-Technical Abstract

Cancers occur when normal cells grow and divide in an uncontrolled fashion. Many human cancers have been shown to have mutations in proteins that control cell growth and division. These mutations are required for the involved cell to become a cancer. One such mutant "cancer" protein is called Ras. The Ras protein is mutated in many human cancers including cancers of the colon, rectum, pancreas and lung, as well as in melanomas. There is evidence that the immune system can fight cancer. One of the cells in the immune system, a killer T cell, can recognize cancer cells that are making mutant proteins, including Ras. However, these killer cells do not appear to be stimulated effectively in cancer patients.

GlobeImmune has developed a novel immunotherapy product that stimulates killer T cells to fight cancers making the mutant Ras protein. To do this GlobeImmune's scientists use recombinant DNA technology to modify ordinary Baker's yeast such that the yeast produce the mutant Ras protein. The yeast are heat killed. The product is called GI-4000. Extensive studies in mice using the GI-4000 product have shown that injection of the heat-killed yeast stimulate a potent killer T cell response that can eradicate cancer cells that are making mutant Ras. In animal safety studies that are required by the FDA, GI-4000 has been shown to have minimal toxicity - mostly limited to reactions at the injection site.

GlobeImmune is proposing to do a clinical trial in cancer patients with GI-4000. In brief, GI-4000 will be injected under the skin of cancer patients whose cancers have been shown to be making the mutant Ras protein. The cancer patients will be monitored for toxic effects, Ras-specific immune responses, and any therapeutic benefits related to injection of GI-4000.